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Patents Act 1990

Cochlear Limited

PROVISIONAL SPECIFICATION

Invention Title:

Cochlear electrode array

The invention is described in the following statement:

Field of the Invention

The present invention relates to an implantable tissue-stimulating prosthesis such as a cochlear implant system. In particular, the invention relates to a electrode carrier member for such a prosthesis.

Background of the Invention

Delivery of electrical stimulation to appropriates locations within the body can be used for a variety of purposes.

For example, function electrical stimulation (FES) systems can be used to deliver electrical pulses to certain muscles of a recipient so leading to a controlled movement of the limb of such a recipient.

Electrical stimulation of the cochlea using cochlear implant systems can also be used to directly deliver electrical stimulation to the auditory nerve fibres, thereby allowing the brain to perceive a hearing sensation resembling the natural hearing sensation normally delivered to the auditory nerve.

Cochlear implant systems have typically consisted of two main components, an external component commonly referred to as a processor unit and an internal implanted component commonly referred to as a receiver/stimulator unit. Traditionally, both of these components have cooperated together to provide the sound sensation to a recipient.

The external component has traditionally consisted of a microphone for detecting sounds, such as speech and environmental sounds, a speech processor that converts the detected sounds, particularly speech, into a coded signal, a power source such as a battery, and an external transmitter antenna.

The coded signal output by the speech processor is transmitted transcutaneously to the implanted receiver/stimulator unit situated within a recess of the temporal bone of the recipient. This transcutaneous transmission occurs via the external transmitter antenna which is positioned to communicate with an implanted receiver antenna provided with the receiver/stimulator unit.

This communication serves two essential purposes, firstly to transcutaneously transmit the coded sound signal and secondly to provide power to the implanted receiver/stimulator unit. Conventionally, this link has been in the form of a radio frequency (RF) link, but other such links have been proposed and implemented with varying degrees of success.

The implanted receiver/stimulator unit traditionally includes a receiver antenna that receives the coded signal and power from the external processor component, and a stimulator that processes the coded signal and outputs a stimulation signal to an intracochlear electrode assembly mounted to a carrier member which applies the electrical stimulation directly to the auditory nerve producing a hearing sensation corresponding to the original detected sound.

To position the carrier member that is mounting the electrode assembly, a surgeon typically forms a cochleostomy before gripping the member by hand or with a tool and then inserting a leading end of the carrier through the cochleostomy and into preferably the scala tympani of the cochlea.

One potential problem during the insertion process is the potential for the carrier member to be damaged and/or rendered at least partially inoperative due to the handling that the member receives prior to and during the insertion procedure. The present invention is directed to ensuring the potential for inadvertent damage to the carrier member is minimised during the insertion procedure.

Further, currently available carrier members are not easily adaptable for use with an insertion tool such as that described in the present applicant's pending International Application No PCT/AU03/00229. The present invention is directed to ensuring that the carrier member is shaped in such a manner where the member can easily be adapted for use with such a tool.

Any discussion of documents, acts, materials, devices, articles or the like which has been included in the present specification is solely for the purpose of providing a context for the present invention. It is not to be taken as an admission that any or all of these matters form part of the prior art base or were common general knowledge in the

field relevant to the present invention as it existed before the priority date of each claim of this application.

Summary of the Invention

Throughout this specification the word "comprise", or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated element, integer or step, or group of elements, integers or steps, but not the exclusion of any other element, integer or step, or group of elements, integers or steps.

According to a first aspect, the present application is directed to a first invention comprising an implantable tissue-stimulating prosthesis comprising:

an elongate carrier member having a distal end, a proximal end, and at least one electrode positioned thereon; and

a lead extending from said carrier member and enclosing at least one electrical conduction means extending from said at least one electrode;

the prosthesis being characterised in that the carrier member has a holding region that is adapted to be held during placement of the carrier member in a recipient.

In one embodiment, the holding region is positioned distal the distal end of the carrier member. In one embodiment, the holding region is positioned at or near the proximal end of the carrier member.

The holding region can comprise a holding member extending outwardly from the carrier member. The holding member can extend longitudinally along the carrier member for a distance near or at the proximal end of the carrier member. The holding region can extend outwardly for a distance less than, greater than, or about equal to the width of the carrier member.

In one embodiment, the holding member can have at least two sidewalls with the holding member tapering in width for a portion of its height away from the carrier member. The holding member can further have a curved upper surface. In a still further embodiment, the holding member can have at least a region thereof where the member does not decrease or increase in width. This region can constitute anywhere between about 20% and 80%, more preferably about 50%, of the height of the holding

member. In this region, the sidewalls of the holding member can be substantially parallel or exactly parallel.

In one embodiment, the holding member further comprises a support member that connects the holding member to the carrier member. In one embodiment, the support member can have a length about equal to or less than the maximum length of the holding member. In a further embodiment, the support member can have a width less than the maximum width of the holding member. In one embodiment, the support member acts as a support rail and functions in a manner described below.

The holding member can be formed integrally with the body of the carrier member. In another embodiment, the holding member can be formed separately to the carrier member and then joined to the carrier member. The holding member can be removably or non-removably joined to the carrier member. In yet another embodiment, the holding member can be rotatably mounted to the carrier member. This allows the position of the holding member to be rotated around the carrier member to a position that suits the surgeon implanting the prosthesis. Still further, the holding member can be slidably mounted to the carrier member and so be adjustable in position along at least a portion of the length of the carrier member. Still further, the holding member can be both slidably and rotatably mounted to the carrier member.

In a still further embodiment, the holding member can be a solid member. In another embodiment, the holding member can be at least partially hollow and comprise a two or more walls, with the member being at least partially filled with air or another material.

In yet a further embodiment, at least a portion of the holding member has some form of indicia that identifies the holding member on the carrier member. A surgeon using the carrier member can be informed by advice provided on the packaging or the like to note the position of the holding member. In one embodiment, the indicia can be the shape of the member, the shape being clearly different to that of the remainder of the carrier member.

In another embodiment, the indicia can be the colour of at least a part of and preferably the entire holding member. In one embodiment, the colour is preferably different to the colour of the carrier member. For example, the holding member can be

white in colour whereas the carrier member can have a different colour or indeed be essentially colourless due to being formed from a translucent or transparent material. The colour can be applied to the holding member or can be the inherent colour of the material selected to form the holding member. In one embodiment, a suitable filler, such as white titanium dioxide, can be mixed with a suitable silicone to form a white holding member.

In a still further embodiment, the indicia can be the tactility of the holding member in comparison to the tactility of the remainder of the carrier member. This difference in feel can be achieved through selection of the material comprising at least part of the holding member. For example, a holding member formed from a plastics material, such as polypropylene, will have a different tactility to that of a carrier member formed from a suitable biocompatible silicone.

In another embodiment, the surface finish of the holding member can be different to that of the carrier member. For example, undulations or channels formed in the holding member would present a different tactility to the normally relatively smooth finish of the carrier member.

It will be appreciated that the holding member could have two or more of the features defined above. For example, the holding member could have both a different colour and have a different tactility to that of the carrier member.

In yet another embodiment, the holding region could be identified by a surgeon through being some form of indicia on the carrier member. In this embodiment, the holding region need not have the features defined above with respect to the holding member. In one embodiment, the indicia can be the shape of the region, with the shape being clearly different to that of the remainder of the carrier member.

In another embodiment, the indicia can be the colour of at least a part of and preferably the entire holding region. In one embodiment, the colour is preferably different to the colour of the carrier member. For example, the holding region can be white in colour whereas the carrier member can have a different colour or indeed be essentially colourless due to being formed from a translucent or transparent material. The colour can be applied to the holding region or can be the inherent colour of the material selected to form the holding region. In one embodiment, a suitable filler, such

as white titanium dioxide, can be mixed with a suitable silicone to form a white holding region part of the carrier member.

In a still further embodiment, the indicia can be the tactility of the holding region in comparison to the tactility of the remainder of the carrier member. This difference in feel can be achieved through selection of the material comprising at least part of the holding region. For example, a holding region formed from a plastics material, such as polypropylene, will have a different tactility to that of a carrier member formed from a suitable biocompatible silicone.

In another embodiment, the surface finish of the holding region can be different to that of the carrier member. For example, undulations or channels formed in the holding region would present a different tactility to the normally relatively smooth finish of the carrier member.

It will be appreciated that the holding region could have two or more of the features defined above. For example, the region could have both a different colour and have a different tactility to that of the carrier member.

In a preferred embodiment, the holding region does not have one or more electrical conduction means passing therethrough. Indeed, it is preferred that the holding region is free of any parts making up the electrode array that may be damaged through handling of the carrier member in that region.

In one embodiment, the electrical conduction means preferably comprises one or more electrically conducting wires that extend from said at least one electrode through the body of the carrier member towards the proximal end thereof. In a preferred embodiment, one or more wires extend from each electrode on the carrier member. The wires can be formed from a suitable electrically conducting metal, preferably a suitable biocompatible electrically conducting metal. Other suitable electrically conductive materials for use as conductive pathways through the carrier member can be envisaged, including semi-conducting materials and electrically conducting polymers.

In a still further embodiment, the holding region is preferably manipulable by the fingers of a surgeon. In another embodiment, the holding region is manipulable by suitable surgical tools, including forceps or tweezers, hooks, clamps and suction tools.

In a preferred embodiment, the holding region is manipulable by both a surgeon's fingers and tools handled by a surgeon thereby ensuring the carrier member can be used by any surgeon irrespective of whether that surgeon prefers to handle the carrier member by hand or with a tool during the implantation procedure.

In a further embodiment, the carrier member is preferably insertable using an insertion tool. The insertion tool preferably supports the carrier member and assists in delivering the leading end of the carrier member to the insertion location. In one embodiment, the carrier member can be adapted to be supported in a slotted tube, that is, a tube having a slot formed therein and extending over at least a portion and preferably the entire length of the tube. In one embodiment, the tube can be cylindrical.

As mentioned above, where the carrier member has a holding member, the holding member can comprise a support rail. The support rail can be adapted to extend through the slot in the slotted tube when the carrier member is placed within the tube. This arrangement results in the carrier member being in the tube, the rail extending through the slot, and the remainder of the holding member being external the tube.

While described in more detail below, the prosthesis according to the present invention can be cochlear implant. In this case, the carrier member can be adapted to be inserted through a cochleostomy and into the cochlea of a recipient. In this case, the insertion tool can comprise the tool as described in the present applicant's pending International Application No PCT/AU03/00229.

The tissue-stimulating prosthesis can comprise a functional electrical stimulation (FES) prosthesis. In another embodiment, the prosthesis can be adapted to deliver stimulation to the brain.

As mentioned, the tissue-stimulating prosthesis can be cochlear implant. For the purposes of the remainder of this specification, the present invention will be described with reference to such an implant. It is, however, to be understood that the features described hereunder could be suitably modified and utilised in the other noted applications.

The elongate carrier member preferably has a plurality of electrodes mounted thereon. In one embodiment, the electrodes are mounted in a longitudinal array. As described, each of the electrodes have at least one wire extending from each electrode back towards the trailing end of the carrier member.

The elongate carrier member is preferably formed from a resiliently flexible material. In one embodiment, the carrier member can be preformed from a plastics material with memory.

In a preferred embodiment, the orientation of the carrier member as it is firstly inserted through the cochleostomy is preferably substantially straight. More preferably, the implantable orientation is straight. Following completion of implantation, the carrier member preferably adopts a spirally curved configuration that matches the spiral nature of the scala tympani of the human cochlea. The carrier member is preferably pre-formed with this spiral configuration and is then straightened either during manufacture and packaging of the device or prior to implantation. For example, the carrier member can be straightened so as to be mounted in an insertion tool.

In a preferred embodiment, the elongate carrier member is formed from a suitable biocompatible material. In one embodiment, the biocompatible material can be a silicone, such as a flexible silicone elastomer-Silastic. Silastic MDX 4-4210 is an example of one suitable silicone for use in the formation of the elongate member. In another embodiment, the elongate carrier member can be formed from a polyurethane or similar material.

The cochlear implant electrode assembly device preferably further comprises at least one stiffening element that is adapted to bias the carrier member into at least a substantially straight configuration prior to and during initial insertion of the carrier member through the cochleostomy. The stiffening element is preferably positioned during manufacture of the device and serves to straighten the carrier member that would otherwise preferentially adopt a spirally curved configuration.

The stiffening element is preferably formed of a material that is relatively stiffer than the material of the carrier member.

The stiffening element is preferably formed from a non-bioresorbable material. In this embodiment, the stiffening element can comprise a metallic or plastic stylet. The stylet can extend through a single lumen extending within at least a portion of the length, more preferably a majority of the length, of the elongate carrier member.

In one embodiment, the stylet can be formed from a biocompatible material, such as a metal or metallic alloy. In a preferred embodiment, the metal stylet is formed from platinum.

In one embodiment, the lumen for the stylet can be cylindrical and also can have an opening formed therein. In a further embodiment, the lumen extends from an opening distal the leading end to a position at or adjacent the leading end. The lumen for the stylet preferably does not extend through the holding region of the carrier member.

The lumen can be cylindrical or have another cross-sectional shape. In the case where the metal stylet is used, the stylet can extend out of the opening allowing the stylet to be manipulated and removed from the lumen during the insertion procedure of the carrier member.

During use, the leading end of the carrier member is preferably inserted into the cochlea through a cochleostomy and is inserted firstly towards the first basal turn of the cochlea.

In one embodiment, where the carrier member has a stylet, and the carrier member is advanced through the cochleostomy, the stylet preferably remains within the carrier member and is also advanced into the cochlea. As such, there is preferably no relative movement of the carrier member to the stylet during insertion of the carrier member and up until the leading end is positioned at or near the first basal turn.

Once the surgeon has advanced the device to this position, the stylet is then held in place as the carrier member is held at its holding region and then advanced relatively forwardly still further into the cochlea. As the stylet is held, the portion of the carrier member adjacent the leading end slides forwardly off the stylet. As this occurs, that portion of the carrier member begins to adopt its preferential curved configuration so

causing the leading end to move further into the spiral-shaped scala tympani of the cochlea and preferably without striking the wall of the basal turn of the cochlea.

Once the electrode carrier member has been advanced the desired distance into the cochlea, the carrier member can be held in place by holding the holding region as the stylet is withdrawn rearwardly out of the lumen and back out through the cochleostomy.

By advancing the carrier member at least partially off the stylet, the leading portion of the carrier member is free to start to adopt its preferential curved configuration and so enables the elongate carrier member to be inserted into the cochlea in a way which minimises, and preferably eliminates, trauma to the walls of the cochlea.

On complete removal of the stylet, the elongate carrier member is free to adopt the fully curved pre-formed orientation along its entire length and is so placed in its final position in the cochlea.

The present invention assists a surgeon in performing a cochlear implantation in that it identifies which portion of the carrier member should be held during the implantation procedure if the potential for damage to the member is to be minimised. The reduction in potential for damage to the carrier member should lead to an even lower rate of implant failure following implantation than hitherto has been the case.

In a further aspect, the present invention comprises a method of implanting a tissue-stimulating prosthesis as defined herein in a desired location in a recipient.

In one embodiment, the method can comprise implanting a carrier member as defined herein in the cochlea of a recipient.

In this aspect, the method can comprise a step of forming a cochleostomy, accessing the cochleostomy, gripping the carrier member at the holding region, and inserting the substantially straight carrier member through the cochleostomy and into the cochlea. Once the carrier member is at a desired location, the carrier member can be advanced relatively forwardly off the stylet. As it is advanced forward, the carrier member is free to at least to begin to adopt its preferential curved configuration, so

facilitating relatively atraumatic further insertion of the carrier member into the cochlea and also minimising the potential for damage to the member. Once the carrier member has been advanced relatively forwardly to its desired location, the stiffening element can be withdrawn leaving the carrier member in place in the cochlea.

Once implanted, the electrodes of the carrier member can receive stimulation signals from a stimulator unit. The stimulator unit is preferably electrically connected to the elongate carrier member by way of the electrical lead. The lead can include the one or more wires extending from each electrode of the array mounted on the elongate member.

In one embodiment, the lead can extend from the elongate member to the stimulator unit or at least the housing thereof. In one embodiment, the lead is continuous with no electrical connectors, at least external the housing of the stimulator unit, required to connect the wires extending from the electrodes to the stimulator unit. One advantage of this arrangement is that there is no requirement for the surgeon implanting the device to make the necessary electrical connection between the wires extending from the electrodes and the stimulator unit.

The stimulator unit is preferably positioned within a housing that is implantable within the recipient. The housing for the stimulator unit is preferably implantable within a recess in the bone behind the ear posterior to the mastoid.

When implanted, the housing preferably contains, in addition to the stimulator unit, a receiver unit. The receiver unit is preferably adapted to receive signals from a controller. The controller is, in use, preferably mounted external to the body of the recipient such that the signals are transmitted transcutaneously through the skin of the recipient.

Signals can preferably travel from the controller to the receiver unit and vice versa. The receiver unit can include a receiver antenna, such an antenna coil, adapted to receive radio frequency (RF) signals from a corresponding transmitter antenna, such as an antenna coil, worn externally of the body. The radio frequency signals can comprise frequency modulated (FM) signals. While described as a receiver antenna, the receiver antenna can preferably transmit signals to the transmitter antenna which receives the signals.

The transmitter antenna coil is preferably held in position adjacent the implanted location of the receiver antenna coil by way of respective attractive magnets mounted centrally in, or at some other position relative to, the coils.

The external controller can comprise a speech processor adapted to receive signals output by a microphone. During use, the microphone is preferably worn on the pinna of the recipient, however, other suitable locations can be envisaged, such as a lapel of the recipient's clothing. The speech processor encodes the sound detected by the microphone into a sequence of electrical stimuli following given algorithms, such as algorithms already developed for cochlear implant systems. The encoded sequence is transferred to the implanted receiver/stimulator unit using the transmitter and receiver antennae. The implanted receiver/stimulator unit demodulates the signals and allocates the electrical pulses to the appropriate attached electrode by an algorithm which is consistent with the chosen speech coding strategy.

The external controller further comprises a power supply. The power supply can comprise one or more rechargeable batteries. The transmitter and receiver antennae are used to provide power via transcutaneous induction to the implanted receiver/stimulator unit and the electrode array.

While the implant system can rely on external componentry, in another embodiment, the controller, including the microphone, speech processor and power supply can also be implantable. In this embodiment, the controller can be contained within a hermetically sealed housing or the housing used for the stimulator unit.

In a still further aspect, the present invention is a mould for use in the moulding of the implantable tissue-stimulating prosthesis as defined herein. The mould can comprise a cavity into which a biocompatible elastomeric material, such as is defined herein, can be poured and allowed to set.

Brief Description of the Drawings

By way of example only, a preferred embodiment of the invention is now described with reference to the accompanying drawings, in which:

Fig. 1 is a side view of one example of a carrier member of a prior art cochlear implant system;

Fig.2 is one embodiment of a carrier member according to the present invention;

Fig. 3 is another view of a portion of the carrier member of Fig. 2 depicted mounted to a stylet;

Fig. 4 is a simplified cross-sectional view of the carrier member and holding member according to the present invention; and

Fig. 5a and 5b are plan and sectional views of a mould for use in the moulding of a carrier member according to the present invention.

Preferred Mode of Carrying out the Invention

An example of one type of prior art carrier member for use as a component of a cochlear implant system is depicted generally as 10 in Fig. 1. The carrier member 10 has a silicone body 11 having a plurality of electrodes 12 mounted thereon. Electrical connection is made between the electrodes and a stimulator unit through lead 13 that extends out of the body 11 near its proximal end 14.

Figs. 2-4 depict an example of a carrier member according to the present invention generally as 20. In this embodiment, the body 21 of the carrier member 20 has a holding member 22 extending outwardly therefrom.

The holding member 22 extends longitudinally along part of the body 21 and is positioned near the proximal end 24 thereof. In the depicted embodiment, the holding member 22 extends outwardly for a distance slightly greater than the width of the body 21 of the carrier member .

As depicted, the holding member 22 can have two sidewalls with the member 22 tapering in width for a portion of its height away from the body 21 of the carrier member.

The holding member can have a number of different cross-sectional shapes. For example, the holding member can have at least a region thereof where the member does not decrease or increase in width. This region can constitute anywhere between about 20% and 80% of the height of the holding member, more preferably about 50%. In this region, the sidewalls of the holding member can be substantially parallel or parallel.

As depicted, the holding member 22 can further comprises a support rail 25 that is in turn connected to the body 21 of the carrier member. As depicted, the support rail has a length about equal to the maximum length of the holding member 22 and a width that is less than the maximum width of the holding member 22. More detail about the function of the support rail 25 is provided below.

The depicted holding member 22 is formed integrally with the body 21 of the carrier member.

In another embodiment, that is not depicted, the holding member could be formed separately to the carrier member and then joined to the carrier member. The holding member can also be removably or non-removably joined to the carrier member. In yet another embodiment, the holding member can be rotatably mounted to the carrier member. This allows the position of the holding member to be rotated around the carrier member to a position that suits the surgeon implanting the prosthesis. Still further, the holding member can be slidably mounted to the carrier member and so be adjustable in position along at least a portion of the length of the carrier member. Still further, the holding member can be both slidably and rotatably mounted to the carrier member.

While the depicted holding member 22 is a solid member, the member 22 could be at least partially hollow or filled with a different substance to that used to form the sidewalls of the member 22.

The holding member 22 can have some form of indicia that identifies the location of the member on the carrier member to a surgeon about to implant the member 20 in the cochlea of a recipient.

In one embodiment, the indicia can be the shape of the member 22, the shape being clearly different to that of the remainder of the carrier member. The embodiment depicted in Figs. 2 and 3 has this attribute.

In another embodiment, the indicia can be the colour of at least a part of and preferably the entire holding member 22. For example, the colour of the holding member can be different to the colour of the body 21 of the carrier member. For example, the holding member 22 can be white in colour whereas the carrier member can have a different colour or indeed be essentially colourless due to being formed from a translucent or transparent material, such as a silicone.

The colour can be applied to the holding member 22 or can be the inherent colour of the material selected to form the holding member 22. In one embodiment, a suitable filler, such as white titanium dioxide, can be mixed with a suitable silicone to form a white holding member.

In a still further embodiment, the indicia can be the tactility of the holding member 22 in comparison to the tactility of the remainder of the carrier member. This difference in feel can be achieved through selection of the material comprising at least part of the holding member. For example, a holding member formed from a plastics material, such as polypropylene, will have a different tactility to that of a carrier member formed from a suitable biocompatible silicone.

In another embodiment, the surface finish of the holding member 22 can be different to that of the carrier member. For example, undulations or channels formed in the holding member would present a different tactility to the normally relatively smooth finish of the carrier member.

It will be appreciated that the holding member could have two or more of the features defined above. For example, the holding member could have both a different colour and have a different tactility to that of the carrier member.

As depicted, a lead 26 extends from the carrier member 20. The lead contains a plurality of wires that extend from the electrodes back through the body 21 and then to the stimulator unit. The lead 26 is positioned such that the wires passing therethrough do not pass through the holding member 22. As such, the carrier member 20 can be

gripped by the member 22 without risk of damaging the relatively fine wires that are passing through the body 21 of the carrier member and into the lead 26.

The holding member 22 is manipulable both by the fingers of a surgeon but also by suitable surgical tools, including forceps or tweezers, hooks, clamps and suction tools. This ensures that the carrier member can be used by any surgeon irrespective of whether that surgeon prefers to handle the carrier member by hand or with a tool during the implantation procedure.

The depicted carrier member 20 is also insertable using an insertion tool. Such a tool supports the carrier member 20 and assists in delivering the leading end of the carrier member to the insertion location. In one embodiment, the carrier member can be adapted to be supported in a cylindrical slotted tube, that is, a tube having a slot formed therein and extending over at least a portion and preferably the entire length of the tube.

As mentioned above, the holding member 22 has a support rail 25. The support rail 25 can be adapted to extend through the slot in the slotted tube when the carrier member 20 is placed within the tube. This arrangement results in the carrier member 20 being in the tube, the rail 25 extending through the slot, and the remainder of the holding member being external the tube.

While the depicted prosthesis is a cochlear implant, the tissue-stimulating prosthesis can comprise a functional electrical stimulation (FES) prosthesis. In another embodiment, the prosthesis can be adapted to deliver stimulation to the brain.

As depicted, the elongate carrier member 20 has a plurality of electrodes 12 mounted thereon.

The body 21 of the elongate carrier member is formed from a resiliently flexible material with the orientation of the carrier member as it is firstly inserted through the cochleostomy being substantially straight. Following completion of implantation, the carrier member 20 adopts a spirally curved configuration that matches the spiral nature of the scala tympani of the human cochlea. The carrier member 20 is pre-formed with this spiral configuration and is then straightened either during manufacture and packaging of the device or prior to implantation.

The elongate carrier member 20 can be formed from a suitable biocompatible material. In one embodiment, the biocompatible material can be a silicone, such as a flexible silicone elastomer-Silastic. Silastic MDX 4-4210 is an example of one suitable silicone for use in the formation of the elongate member. In another embodiment, the elongate carrier member can be formed from a polyurethane or similar material.

As depicted in Fig. 3, the carrier member can receive a platinum stylet 27 that is adapted to bias the body 21 of the carrier member 20 into at least a substantially straight configuration prior to and during initial insertion of the carrier member through the cochleostomy. The stylet 27 is preferably positioned during manufacture of the device and serves to straighten the carrier member 20 that would otherwise preferentially adopt a spirally curved configuration.

The stylet is received in a lumen within the body 21 of the carrier member. The lumen extends from an opening distal the leading end to a position at or adjacent the leading end. The lumen for the depicted stylet 27 does not extend through the holding member 22.

During use, the leading end of the carrier member 20 is inserted into the cochlea through a cochleostomy and is inserted firstly towards the first basal turn of the cochlea. During this initial procedure, the stylet preferably remains within the carrier member and is also advanced into the cochlea. As such, there is preferably no relative movement of the carrier member to the stylet 27 during insertion of the carrier member and up until the leading end is positioned at or near the first basal turn.

Once the surgeon has advanced the device to this position, the stylet 27 is then held in place as the carrier member is held at its holding member 22 and then advanced relatively forwardly still further into the cochlea. As the stylet is held, the portion of the carrier member adjacent the leading end slides forwardly off the stylet. As this occurs, that portion of the carrier member begins to adopt its preferential curved configuration so causing the leading end to move further into the spiral-shaped scala tympani of the cochlea and preferably without striking the wall of the basal turn of the cochlea.

Once the electrode carrier member has been advanced the desired distance into the cochlea, the carrier member can be held in place by holding the holding member 22 as the stylet is withdrawn rearwardly out of the lumen and back out through the cochleostomy.

By advancing the carrier member at least partially off the stylet, the leading portion of the carrier member is free to start to adopt its preferential curved configuration and so enables the elongate carrier member to be inserted into the cochlea in a way which minimises, and preferably eliminates, trauma to the walls of the cochlea.

On complete removal of the stylet 27, the elongate carrier member 20 is free to adopt the fully curved pre-formed orientation along at least part of its entire length and is so placed in its final position in the cochlea.

The present invention assists a surgeon in performing a cochlear implantation in that it identifies which portion of the carrier member should be held during the implantation procedure if the potential for damage to the member 20 is to be minimised. The reduction in potential for damage to the carrier member 20 should lead to an even lower rate of implant failure following implantation than hitherto has been the case.

Once implanted, the electrodes 12 of the carrier member 20 receive stimulation signals from a stimulator unit. The stimulator unit is preferably electrically connected to the elongate carrier member 20 by way of the electrical lead 26. The lead 26 can be continuous with no electrical connectors, at least external the housing of the stimulator unit, required to connect the wires extending from the electrodes 12 to the stimulator unit. One advantage of this arrangement is that there is no requirement for the surgeon implanting the device to make the necessary electrical connection between the wires extending from the electrodes 12 and the stimulator unit.

The stimulator unit is preferably positioned within a housing that is implantable within the recipient. The housing for the stimulator unit is preferably implantable within a recess in the bone behind the ear posterior to the mastoid. When implanted, the housing preferably contains, in addition to the stimulator unit, a receiver unit. The receiver unit is preferably adapted to receive signals from a controller. The controller

is, in use, preferably mounted external to the body of the recipient such that the signals are transmitted transcutaneously through the skin of the recipient.

Signals can preferably travel from the controller to the receiver unit and vice versa. The receiver unit can include a receiver antenna, such an antenna coil, adapted to receive radio frequency (RF) signals from a corresponding transmitter antenna, such as an antenna coil, worn externally of the body. The radio frequency signals can comprise frequency modulated (FM) signals. While described as a receiver antenna, the receiver antenna can preferably transmit signals to the transmitter antenna which receives the signals.

The transmitter antenna coil is preferably held in position adjacent the implanted location of the receiver antenna coil by way of respective attractive magnets mounted centrally in, or at some other position relative to, the coils.

The external controller can comprise a speech processor adapted to receive signals output by a microphone. During use, the microphone is preferably worn on the pinna of the recipient, however, other suitable locations can be envisaged, such as a lapel of the recipient's clothing. The speech processor encodes the sound detected by the microphone into a sequence of electrical stimuli following given algorithms, such as algorithms already developed for cochlear implant systems. The encoded sequence is transferred to the implanted receiver/stimulator unit using the transmitter and receiver antennae. The implanted receiver/stimulator unit demodulates the signals and allocates the electrical pulses to the appropriate attached electrode by an algorithm which is consistent with the chosen speech coding strategy.

The external controller further comprises a power supply. The power supply can comprise one or more rechargeable batteries. The transmitter and receiver antennae are used to provide power via transcutaneous induction to the implanted receiver/stimulator unit and the electrode array.

While the implant system can rely on external componentry, in another embodiment, the controller, including the microphone, speech processor and power supply can also be implantable. In this embodiment, the controller can be contained within a hermetically sealed housing or the housing used for the stimulator unit.

Figs. 5a and 5b depict a mould 40 for use in the moulding of the carrier member 10. A suitable biocompatible elastomeric material, such as a flexible silicone elastomer-Silastic can be poured into the cavity 41 in the mould and allowed to at least partially set. In one embodiment of this method of manufacture, the electrodes 12 and lead 26 would be positioned in the cavity 41 prior to the Silastic being poured into the cavity around the electrodes 12 and the lead 26.

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

Dated this sixteenth day of April 2003

Cochlear Limited
Patent Attorneys for the Applicant:

F B RICE & CO

Fig. 1 - PRIOR ART

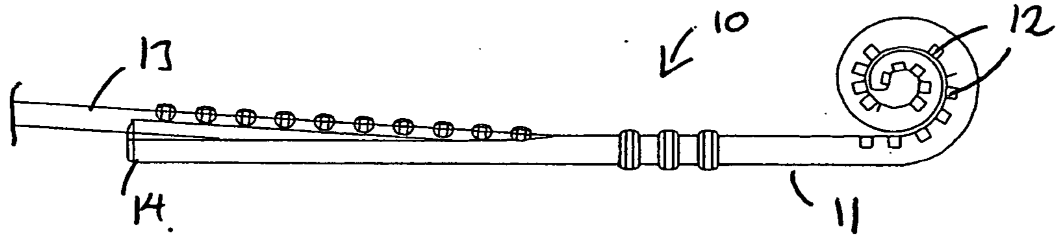
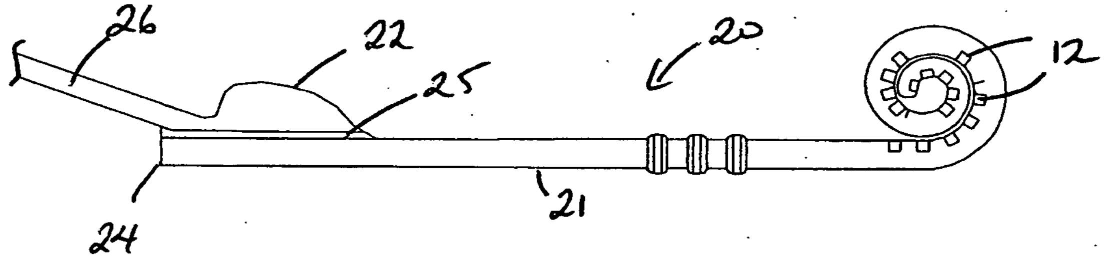


Fig. 2



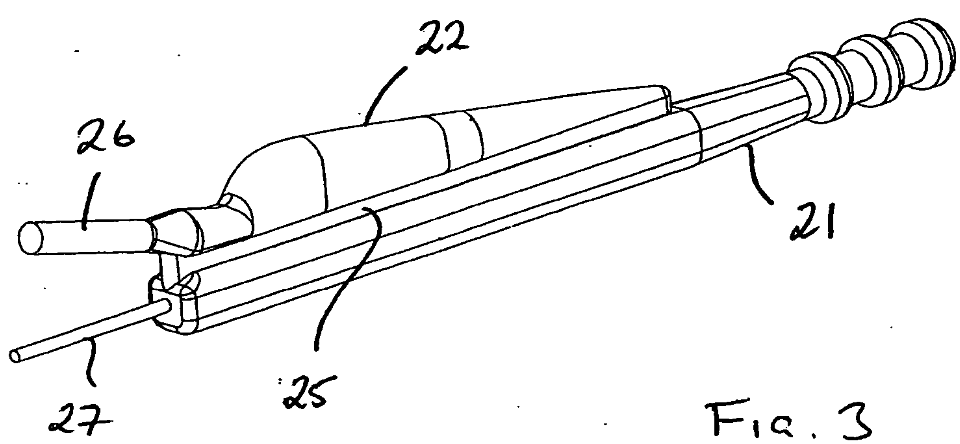
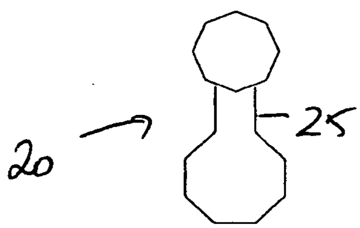


Fig. 3

Fig. 4



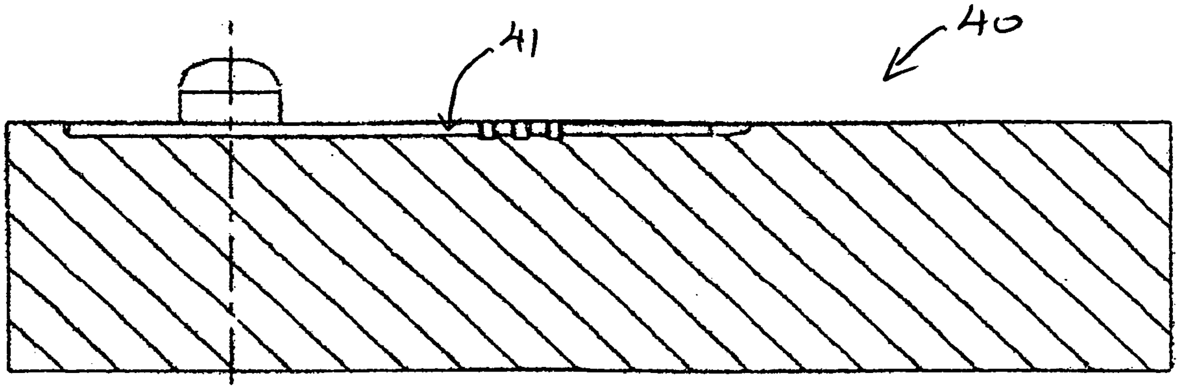


Fig. 5b

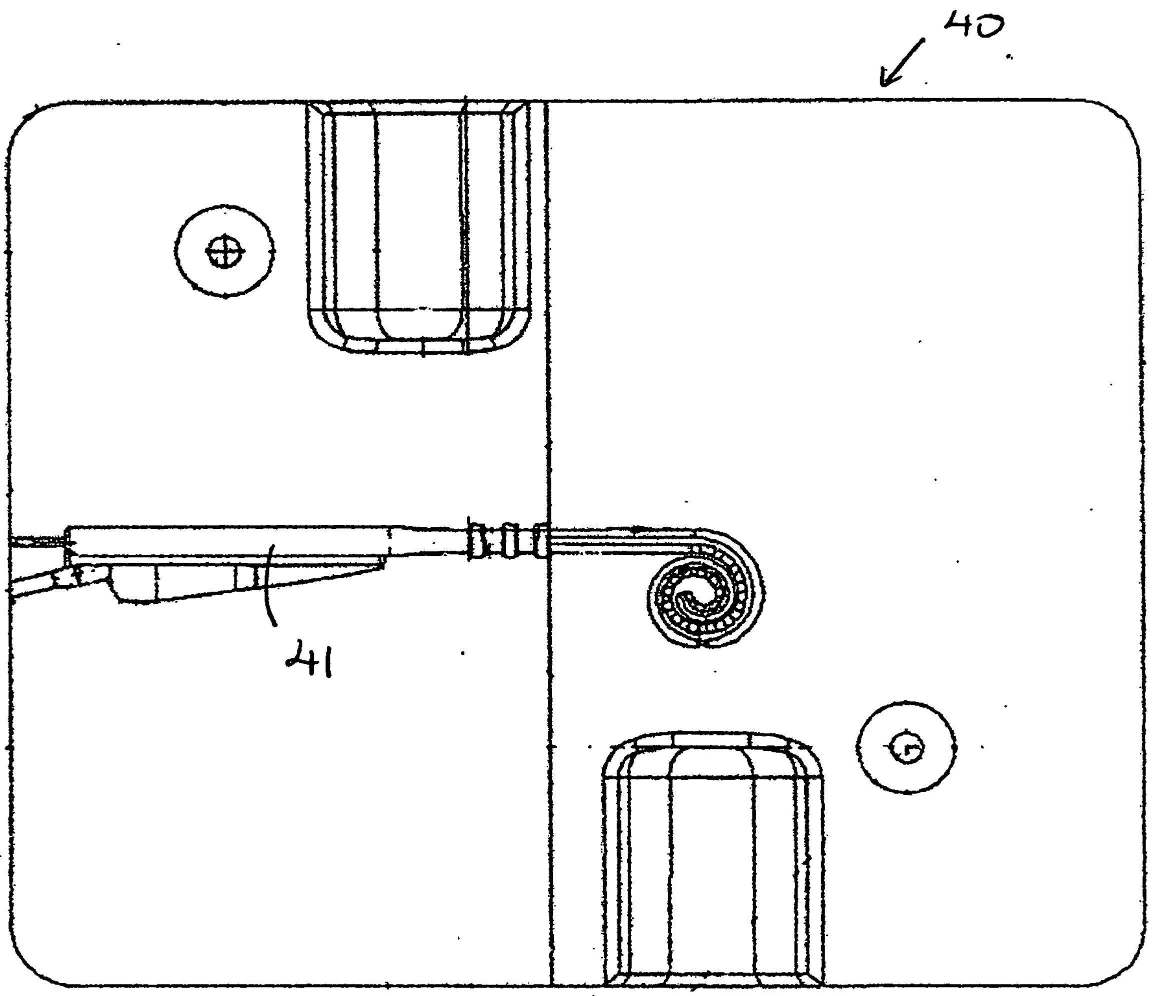


Fig. 5a.

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